



RECEIVED

JUN 06 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 00-505-I)

TECH CENTER 1600/2900

RECEIVED

JUN 30 2002

TECH CENTER 1600/2900

In re Application of:

Progulske-Fox, et al.

Serial No.: 10/092,243

Filed: March 6, 2002

For: **Identification of Microbial Polynucleotides  
Expressed During Infection of a Host**

Examiner: TBA

Art Unit: 1653

TRANSMITTAL LETTER

Asst. Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In regard to the above identified application,

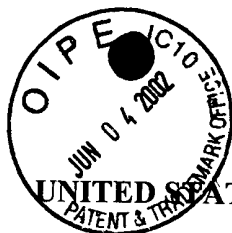
1. We are transmitting herewith the attached:
  - a) Information Disclosure Statement;
  - b) PTO Form 1449 and 27 cited references;
  - c) Return postcard
2. With respect to fees:
  - a) No fee is due at this time.
  - b) Please charge any underpayment or credit any overpayment our Deposit Account, No. 13-2490.
3. GENERAL AUTHORIZATION: Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.
4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Asst. Commissioner for Patents, Washington, D.C. 20231 on May 28, 2002.

Date: May 28, 2002

Respectfully submitted,

Lisa M.W. Hillman

Registration No. 43,673



UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 00-505-I)

RECEIVED  
JUN 06 2002  
TECH CENTER 1600/2900  
PATENT

In the Application of:

Progulske-Fox, et al.

Serial No.: 10/092,243

Filed: March 6, 2002

For: Identification of Microbial  
Polynucleotides Expressed  
During Infection of a Host

Art Unit: 1653

Examiner: To be assigned

TECH CENTER 1600/2900

OCT 30 2002

RECEIVED

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to the duty of disclosure provided by 35 C.F.R. § 1.56 and §§ 1.97-98, the applicants wish to make the following references of record in the above-identified application. Copies of the references are enclosed. Copies are also listed in the PTO-1449 form enclosed herewith. It is requested that the documents be given careful consideration and that they be cited of record in the prosecution history of the present application so that they will appear on the face of the patent issuing from the present application.

In the judgment of the undersigned, portions of the references may be material to the examination of the pending claims, however no such admission is intended. 37 C.F.R. 1.97 (h). The references have not been reviewed in sufficient detail to make any

other representation and, in particular, no representation is indented as to the relative importance of any portion of the references. This Statement is not a representation that the cited references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. sections 102 or 103.

### **CITED REFERENCES**

#### **Foreign Documents**

| <b><u>Document<br/>Number</u></b> | <b><u>Date</u></b> | <b><u>Name</u></b> | <b><u>Country</u></b> |
|-----------------------------------|--------------------|--------------------|-----------------------|
| WO 98/30910                       | 7/16/98            | Bickel, et al.     | PCT                   |
| WO 99/05293                       | 2/4/99             | Bancroft, et al.   | PCT                   |
| WO 98/46738                       | 10/22/98           | Weil, et al.       | PCT                   |
| WO 99/32633                       | 7/1/99             | Milhausen, et al.  | PCT                   |

#### **Other Documents**

- 1) Ebersole, et al., "*An ELISA for Measuring Serum Antibodies to Actinobacillus Actinomycetemcomitans*", *Journal of Periodontal Research*, Vol. 15, pp. 621-632, 1980
- 2) Tsai, et al., "*Serum Neutralizing Activity Against Actinobacillus Actinomycetemcomitans Leukotoxin in Juvenile Periodontitis*", *Journal of Clinical Periodontology*, Vol. 8, pp. 338-348, 1981
- 3) Slots, et al., "*Selective Medium for Isolation of Actinobacillus Actinomycetemcomitans*", *Journal of Clinical Microbiology*, Vol. 15, No. 4, pp. 606-609, 1982
- 4) Ebersole, et al., "*Human Immune Responses to Oral Microorganisms. II. Serum Antibody Responses to Antigens from Actinobacillus Actinomycetemcomitans and the Correlation with Localized Juvenile Periodontitis*", *Journal of Clinical Immunology*, Vol. 3, No. 4, pp. 321-331, 1983
- 5) Brady, et al., "*Two Novel Antigens Associated with Group B Streptococci Identified by a Rapid Two-Stage Radioimmunoassay*", *The Journal of Infectious Diseases*, Vol. 158, No. 5, pp. 965-972, 1988
- 6) Chanyangam, et al., "*Contribution of a 28-Kilodalton Membrane Protein to the Virulence of Haemophilus Influenzae*", *Infection and Immunity*, Vol. 59, No. 2, pp. 600-608, 1991

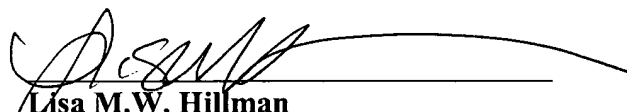
- 7) Mekalanos, "Environmental Signals Controlling Expression of Virulence Determinants in Bacteria", *Journal of Bacteriology*, Vol. 174, No. 1, pp. 1-7, 1992
- 8) Mahan, et al., "Selection of Bacterial Virulence Genes that are Specifically Induced in Host Tissues", *Science*, Vol. 259, pp. 686-688, 1993
- 9) Li, et al., "A New Gene Involved in Stationary-Phase Survival Located at 59 Minutes on the *Escherichia coli* Chromosome", *Journal of Bacteriology*, Vol. 176, No. 19, pp. 6015-6022, 1994
- 10) Fleischmann, et al., "Whole-Genome Random Sequencing and Assembly of *Haemophilus Influenzae* Rd", *Science*, Vol. 269, pp. 496-512, 1995
- 11) Haubek, et al., "Highly Toxic Clone of *Actinobacillus Actinomycetemcomitans* in Geographically Widespread Cases of Juvenile Periodontitis in Adolescents of African Origin", *Journal of Clinical Microbiology*, Vol. 34, No. 6, pp. 1576-1578, 1996
- 12) Valdivia, et al., "Fluorescence-Based Isolation of Bacterial Genes Expressed within Host Cells", *Science*, Vol. 277, pp. 2007-2011, 1997
- 13) Yoshida, et al., "Identification of a Genetic Locus Essential for Serotype b-Specific Antigen Synthesis in *Actinobacillus Actinomycetemcomitans*", *Infection and Immunity*, Vol. 66, No. 1, pp. 107-114, 1998
- 14) Heithoff, et al., "Dissecting the Biology of a Pathogen During Infection", *Trends Microbiology*, Vol. 5, pp. 509-513, 1997
- 15) Smith, "What happens to Bacterial Pathogens in vivo?", *Trends in Microbiology*, Vol. 6, No. 6 pp. 239-243, 1998
- 16) Handfield, et al., "Strategies for Isolation of in vivo Expressed Genes from Bacteria", *FEMS Microbiol. Rev.*, pp. 69-91, 1999
- 17) Chiang, et al., "In vivo Genetic Analysis of Bacterial Virulence", *Annu. Rev. Microbiol.*, Vol. 53, pp. 129-54, 1999
- 18) Slots, et al., "*Actinobacillus Actinomycetemcomitans* and *Porphyromonas Gingivalis* in Human Periodontal Disease: Occurrence and Treatment", *Periodontology 2000*, Vol. 20, pp. 82-121, 1999

- 19) Kinane, et al., "*Humoral Immune Response to Actinobacillus Actinomycetemcomitans and Porphyromonas Gingivalis in Periodontal Disease*", *Periodontology* 2000, Vol. 20, pp. 289-340, 1999
- 20) Hautefort, et al., "*Measurement of Bacterial Gene Expression in vivo*", *Phil. Trnas. R. Soc. London B*, Vol. 355, pp. 601-611 2000
- 21) Suk, et al., "*Borrelia burgdorferi genes selectively expressed in the infected host*", *Proc. Natl. Acad. Sci. USA*, Vol. 92, pp. 4269-4273, 1995
- 22) Handfield, et al., "*Strategies for isolation of in vivo expressed genes from bacteria*", *FEMS Microbiology Reviews*, 23, pp. 69-91, 1999
- 23) PCT International Search Report for PCT/US00/21340

Respectfully submitted,

Date: May 28, 2002

by:

  
**Lisa M.W. Hillman**  
Reg. No. 43,673

FORM PTO-1449  
(Rev. 2-32)

U.S. Department of Commerce  
Patent and Trademark Office

Atty. Docket No.

00-505-I

Serial No.

10/099,243

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)



Applicant:

Progulske-Fox, et al.

Filing Date:

March 6, 2002

Group:

1653

RECEIVED  
JUN 6 2002  
TECH CENTER 1600/2900

U.S. PATENT DOCUMENTS

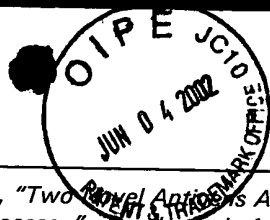
| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date if Appropriate |
|------------------|-----------------|------|------|-------|----------|----------------------------|
|                  |                 |      |      |       |          |                            |
|                  |                 |      |      |       |          |                            |

FOREIGN PATENT DOCUMENTS

|  | Document Number | Date     | Country | Class | Subclass | Translation |    |
|--|-----------------|----------|---------|-------|----------|-------------|----|
|  |                 |          |         |       |          | Yes         | No |
|  | 9 8 3 0 9 1 0   | 7/16/98  | PCT     |       |          |             |    |
|  | 9 9 0 5 2 9 3   | 2/4/99   | PCT     |       |          |             |    |
|  | 9 8 4 6 7 3 8   | 10/22/98 | PCT     |       |          |             |    |
|  | 9 9 3 2 6 3 3   | 7/1/99   | PCT     |       |          |             |    |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

|   |  |
|---|--|
| 1 | Ebersole, et al., "An ELISA for Measuring Serum Antibodies to <i>Actinobacillus Actinomycetemcomitans</i> ", <i>Journal of Periodontal Research</i> , Vol. 15, pp. 621-632, 1980   |
| 2 | Tsai, et al., "Serum Neutralizing Activity Against <i>Actinobacillus Actinomycetemcomitans</i> Leukotoxin in Juvenile Periodontitis", <i>Journal of Clinical Periodontology</i> , Vol. 8, pp. 338-348, 1981  |
| 3 | Slots, et al., "Selective Medium for Isolation of <i>Actinobacillus Actinomycetemcomitans</i> ", <i>Journal of Clinical Microbiology</i> , Vol. 15, No. 4, pp. 606-609, 1982   |
| 4 | Ebersole, et al., "Human Immune Responses to Oral Microorganisms. II. Serum Antibody Responses to Antigens from <i>Actinobacillus Actinomycetemcomitans</i> and the Correlation with Localized Juvenile Periodontitis", <i>Journal of Clinical Immunology</i> , Vol. 3, No. 4, pp. 321-331, 1983 |



030 2002

JUN 06 2002

TECH CENTER 1600/2900

TECH CENTER 1600/2900

|    |  |
|----|--|
| 5  | Brady, et al., "Two Novel Antigen Associated with Group B Streptococci Identified by a Rapid Two-Stage Radioimmunoassay", <i>The Journal of Infectious Diseases</i> , Vol. 158, No. 5, pp. 965-972, 1988   |
| 6  | Chanyangam, et al., "Contribution of a 28-Kilodalton Membrane Protein to the Virulence of <i>Haemophilus Influenzae</i> ", <i>Infection and Immunity</i> , Vol. 59, No. 2, pp. 600-608, 1991   |
| 7  | Mekalanos, "Environmental Signals Controlling Expression of Virulence Determinants in Bacteria", <i>Journal of Bacteriology</i> , Vol. 174, No. 1, pp. 1-7, 1992   |
| 8  | Mahan, et al., "Selection of Bacterial Virulence Genes that are Specifically Induced in Host Tissues", <i>Science</i> , Vol. 259, pp. 686-688, 1993  |
| 9  | Li, et al., "A New Gene Involved in Stationary-Phase Survival Located at 59 Minutes on the <i>Escherichia coli</i> Chromosome", <i>Journal of Bacteriology</i> , Vol. 176, No. 19, pp. 6015-6022, 1994   |
| 10 | Fleischmann, et al., "Whole-Genome Random Sequencing and Assembly of <i>Haemophilus Influenzae</i> Rd", <i>Science</i> , Vol. 269, pp. 496-512, 1995   |
| 11 | Haubek, et al., "Highly Toxic Clone of <i>Actinobacillus Actinomycetemcomitans</i> in Geographically Widespread Cases of Juvenile Periodontitis in Adolescents of African Origin", <i>Journal of Clinical Microbiology</i> , Vol. 34, No. 6, pp. 1576-1578, 1996 |
| 12 | Valdivia, et al., "Fluorescence-Based Isolation of Bacterial Genes Expressed within Host Cells", <i>Science</i> , Vol. 277, pp. 2007-2011, 1997  |
| 13 | Yoshida, et al., "Identification of a Genetic Locus Essential for Serotype b-Specific Antigen Synthesis in <i>Actinobacillus Actinomycetemcomitans</i> ", <i>Infection and Immunity</i> , Vol. 66, No. 1, pp. 107-114, 1998                                      |
| 14 | Heithoff, et al., "Dissecting the Biology of a Pathogen During Infection", <i>Trends Microbiology</i> , Vol. 5, pp. 509-513, 1997  |
| 15 | Smith, "What happens to Bacterial Pathogens in vivo?", <i>Trends in Microbiology</i> , Vol. 6, No. 6 pp. 239-243, 1998   |
| 16 | Handfield, et al., "Strategies for Isolation of in vivo Expressed Genes from Bacteria", <i>FEMS Microbiol. Rev.</i> , pp. 69-91, 1999  |
| 17 | Chiang, et al., "In vivo Genetic Analysis of Bacterial Virulence", <i>Annu. Rev. Microbiol.</i> , Vol. 53, pp. 129-54, 1999  |
| 18 | Slots, et al., " <i>Actinobacillus Actinomycetemcomitans</i> and <i>Porphyromonas Gingivalis</i> in Human Periodontal Disease: Occurrence and Treatment", <i>Periodontology 2000</i> , Vol. 20, pp. 82-121, 1999   |
| 19 | Kinane, et al., "Humoral Immune Response to <i>Actinobacillus Actinomycetemcomitans</i> and <i>Porphyromonas Gingivalis</i> in Periodontal Disease", <i>Periodontology 2000</i> , Vol. 20, pp. 289-340, 1999   |
| 20 | Hautefort, et al., "Measurement of Bacterial Gene Expression in vivo", <i>Phil. Trans. R. Soc. London B</i> , Vol. 355, pp. 601-611 2000   |
| 21 | Suk, et al., " <i>Borrelia burgdorferi</i> genes selectively expressed in the infected host", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 92, pp. 4269-4273, 1995   |
| 22 | Handfield, et al., "Strategies for isolation of in vivo expressed genes from bacteria", <i>FEMS Microbiology Reviews</i> , 23, pp. 69-91, 1999   |
| 23 | PCT International Search Report for PCT/US00/21340   |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.